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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,586	07/11/2001	Rolland-Yves Mauvernay	P-6191	9305

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	13

DATE MAILED: 12/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/807,586	Applicant(s) MAUVERNAY, ROLLAND-YVES	
	Examiner Isis Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,19 and 21-24* is/are rejected.

7)☒ Claim(s) *20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicant's request for extension of time and amendment B, both filed 09/15/2003.

Claims 10-17 have been canceled and claims 18-24 have been added per applicant's amendment A, Paper No. 9.

Claims 18-24 are included in the prosecution.

1. The disclosure is objected to because of the following informalities: in page 2, line 30, applicant is referring to canceled claims 2 and 9.

Appropriate correction is required.

The following new ground of rejection is necessitated by applicant's amendment B, Paper No. 12:

Claim Rejections - 35 USC § 103

2. Claims 18, 19, 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '5,716,988 ('988) in view of US 5, 492,534 ('534).

US '988 teaches a pharmaceutically stable oxaliplatinum preparation comprising aqueous solution of oxaliplatinum in concentration of 1 to 5 mg/ml with pH 4.5-6. The aqueous oxaliplatinum solution is provided as a ready-to-use-preparation in a sealed container (abstract). The oxaliplatinum content in the preparation representing at least 95% of the initial content and the solution remains clear, colorless and free of any precipitation after storage for a pharmaceutically acceptable duration (col.2, lines 9-17). The container can be flexible pouch for infusion (col.2, lines 60-61). Plastic is inherently flexible material. The reference is silent regarding the material of the flexible pouch and not disclosing PVC based material.

US '988 does not teach the material of the bag or the multilayered bag.

US '534 teaches a flexible pouch containing a drug solution that is included in an infusion device and can be stored for prolonged periods without deterioration (abstract; col.5, line 61; col.6, lines 56-63). The flexible pouch contains the drug infusate in a liquid form (col.8, lines 6-7). The pouch is multilayered and the flexible materials of the pouch are typically more vulnerable to attack and degeneration caused by the infusate solution and preferably the layer facing the drug solution is made from polypropylene (col.9, lines 23-31). The reference disclosed that the major advantage of using polypropylene on the drug-facing surface of the pouch is that the infusate solution contacts inert, stable, sterilizable, non-leaching material and essentially impervious to contaminants from outside environment (col.13, lines 47-50). No criticality was shown by applicant in using polyamide in particular as an outer layer of the pouch.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to replace the flexible pouch of US '988 by the multilayered flexible pouch of US '534 that has the layer facing the drug solution is made from polypropylene, motivated by the teaching of US '534 that the major advantage of using polypropylene on the drug facing surface of the pouch is that the infusate solution contacts inert, stable, sterilizable, non-leaching material and essentially impervious to contaminants from outside environment, with reasonable expectation of success of the delivered multilayered pouch having the drug-facing surface is made of polypropylene as container for oxaliplatinum for storage for long period without deterioration.

3. Claims 18-, 19, 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '988 in view of US 6,007,529 ('529).

US '988 teaches a pharmaceutically stable oxaliplatinum preparation comprising aqueous solution of oxaliplatinum in concentration of 1 to 5 mg/ml with pH 4.5-6. The aqueous oxaliplatinum solution is provided as a ready-to-use-preparation in a sealed container (abstract). The oxaliplatinum content in the preparation representing at least 95% of the initial content and the solution remains clear, colorless and free of any precipitation after storage for a pharmaceutically acceptable duration (col.2, lines 9-17). The container can be flexible pouch for infusion (col.2, lines 60-61). Plastic is inherently flexible material. The reference is silent regarding the material of the flexible pouch and not disclosing PVC based material.

US '988 does not teach multilayered bag as recited in claim 11, the inner layer of the bag is made of polyethylene as recited in claims 12, or the multi-compartment pouch as recited in claim 16.

US '529 teaches a flexible transparent container for improved storage of parenterally administrable agents comprising inner container contained in outer envelop. The inner container is made of polypropylene to benefit from its capacity of being inert towards the stored fluids and the outer envelope is flexible multilayered polymeric material (abstract; col.4, line 58-col.5, line 8; col.5, lines 51-54; col.7, lines 4-9). The flexible container has improved barrier against environmental oxygen and moisture and also capable of withstanding sterilization and may be stored for long periods with maintained integrity (col.4, lines 3-12). The inner container can be single or multiple chamber container filled with one or several parenterally administrable agents and has a capacity of separately storing several components (col.4, lines 31-33; col.5, lines 13-15).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a flexible pouch containing oxaliplatinum as disclosed by US '988, and replace the pouch by a multi compartment multilayered flexible pouch having the inner layer made of polypropylene as disclosed by US '529, motivated by the teaching of US '529 that the multiple chamber can be filled by one or more parenterally administrable drugs and has a capacity of separately storing several components and further by its teaching that polypropylene is inert towards the stored fluid barrier and the multilayered container provides barrier against environmental oxygen and moisture and

also capable of withstanding sterilization and may be stored for long periods with maintained integrity, with reasonable expectation of success of the delivered multi compartment multilayered pouch having its inner layer made of polypropylene to maintain oxaliplatinum without deterioration upon prolonged storage.

Response to Arguments

4. Applicant's arguments filed 09/15/2003 have been fully considered but they are not persuasive.

Applicant's argues that the combination of US '988 and US '534 or the combination of US 988 and US '529 do not describe the specific fact that oxaliplatinum is unstable in contact of PVC.

In response to the above argument, the examiner position is that none of the references teaches the PVC in contact to the drugs. The references teach the polypropylene in contact with the drugs for the same reason desired by applicant, i.e. contact of the drug to an inert material. Thus, the art recognized the suitability of polypropylene as bag for drugs because it is inert and stable.

Allowable Subject Matter

5. Claim 15 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The following is a statement of reasons for the indication of allowable subject matter: the cited references do not teach the material of the outer layer of the envelope to be one film of polyamide of 11-amino-undecanoic acid and the inner layer of polypropylene wherein the two layers are bonded by polyolefin film.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048.

The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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